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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/626,142 Filing Date: July 24, 2003 Appellant(s): BURGIO ET AL.

> Loren D. Albin For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/07/2008 appealing from the Office action mailed 09/02/2008.

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(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

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(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

| 5,888,491 | Mitra et al. | 3-1999 |
|-----------|---------------|---------|
| 5,607,663 | Rozzi et al. | 3-1997 |
| 7,025,950 | Majeti et al. | 4-2006 |
| 4,871,786 | Aasen et al. | 10-1989 |
| | | |

www.geo.utexas.edu/courses;387E/PDF/carbonyl!pdf, pp. 1-7 (accessed 12/18/08),

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

 Claims 1-3, 5, 8-11, 14-17, 19, 22, 30-32, 34, 36-43, 45-48, 50-64 and 69-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitra et al. (USP 5.888.491) in view of Maieti et al. (USP 7.025.950).

The primary reference discloses oral compositions (see column 15, lines 38-52) containing the instantly claimed polymers. When applied as dentifrices, the polymers do not contain pendant ethylenically unsaturated groups e.g., pendant 'reactive groups', Deleted: University of Texas, Carbonyl Compounds, Deleted:

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as is clear from the use of the provisional term "may" at column 9, line 59. See also column 16, lines 17. See also working example 1 at column 18, wherein the polymer used plainly does not contain any pendant ethylenically unsaturated groups; compare and contrast this with working example 2, where the inventors took additional steps to provide such groups to a UV curable coating (not a dentifrice). Unit A, present in polymers is comprised of specific groups, include fluoride-releasing groups such as 1-N,N,N-triethylammonium ethyl (meth)acrylate (column 4, lines 41-58) and (meth)acrylic esters of fluoroalkylsulfonamideo alcohols, where the (hydrophobic) fluorine moiety has up to 21 perfluoro-carbons, (see the table of structural formulae provided at column 5 between lines 23-53). Unit B is a modulating group, which is comprised of methacrylic esters of 1-12 carbon alcohols (column 2, lines 11 and column 5, lines 16-18.

As clear from column 19, lines 56-64 of the primary reference, the prior art compositions form hydrophobic coatings on tooth enamel. The compositions are further taught to be useful for the administration of other conventional dentifrice components, e.g., therapeutic agents "such as" fluoride salts (column 15, lines 54-63). The primary reference differs from the instant claims, however, insofar as whitening agents such as peroxides are not specifically disclosed.

The secondary reference teaches that hydrophobic polymers which form coatings on tooth enamel are particularly desirable for the delivery of oral care actives, including fluorides and whitening agents, because they facilitate deposition and retention of same. See column 8, lines 42-56. Useful whitening agents are not limited to hydrogen peroxide, and include other peroxides such as carbamide peroxide, as well as

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peroxyacids, chlorites, etc. (column 9, lines 12-25). From about 0.1% to about 20.0% of teeth whitening agent provide overall cleaning, whitening, stain removal and prevention of stain build-up on teeth (column 8, lines 58-64). Water may be employed in preparation of the composition (column 17, lines 20-27). The method of use comprises contacting a subject's dental enamel surfaces and oral mucosa with the oral compositions; and may be by brushing, rinsing, or contacting the dentifrice by topical oral gel, mouthspray, or other forms such as films or strips (See the passage bridging column 18, line 66 to column 19, line 10).

It would have been obvious to have used a peroxide whitening agent as the oral care active of the primary reference, since the same are known oral care actives as taught by the secondary reference.

2) Claims 6, 7, 12, 13, 20, 21, 23-25, 27-29, 49 and 65-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitra et al. (UDP 5,888,491) in view of Majeti et al. (USP 7,025,950), the combination being taken further in view of Aasen et all (USP 4,861,786).

The primary and secondary references and the motivation for combining their teachings are discussed <u>supra</u>. The compositions suggested by their combined teachings differ from those of the instant claims insofar as they do not include a fluoride releasing group comprising tetrafluroroborate ions.

The tertiary reference teaches that fluoride-releasing monomers containing tetrafluoroborate ions are preferred because of their compatibility with virtually all other

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comonomers. See the passage bridging column 3, lines 62 to column 4, line 8.

Accordingly, it would have been obvious to have used such monomers in the forming the compositions suggested by the combined teachings of the primary and secondary references in order to take advantage of this art-recognized property.

Claims 30-32, 34, 35, 37-43, 45, 50-52 and 60-80 are rejected under 35
 U.S.C. 103(a) as being unpatentable over Rozzi et al. (USP 5,607,663) in view of Majeti et al. (USP7,025,950).

The primary reference is substantially similar to that applied in subsection "1)" supra, except that it teaches the incorporation of hydrophobic hydrocarbon groups such as octadecylacrylate, which the '491 patent lacked (column 5, lines 40-42). Again, note that the use of the provisional term "may" at column 5, line 49; "can't" at column 11, line 43; and "when" at column 12, lines 36 and 46. Again, the prior art discloses dentifrices and teaches the inclusion of oral care actives therein (see the passage bridging column 11, line 60 to column 12, line 19), but differs from the instant claims insofar as peroxide whitening agents are not specifically closed.

The secondary reference is likewise discussed <u>supra</u>. As before, it would have been obvious to have used a peroxide whitening agent as the oral care active of the primary reference since same are known oral care actives as taught by the secondary reference. Art Unit: 1612

Application/Control Number: 10/626,142 (10) Response to Argument

In response to the Final Office Action mailed 06/06/2008 and the Advisory Action dated 09/02/2008, Appellants argue that the Examiner has improperly relied on Mitra et al, for disclosing a polymer that includes a repeating unit including a polar or polarizable group and a repeating unit including a fluoride releasing group, wherein the repeating unit including the polar or polarizable group is different than the repeating unit including the fluoride releasing group. Appellants argue that they have not been able to locate any support for the Examiner's allegation that unit B monomers can be branched or cyclic alcohols. Further, Appellants argue that the branched or cyclic alcohols cited by the Examiner are precursors of the Unit B monomers, and are not monomers themselves, i.e. that once the hydroxy group of the alcohol reacts to form the ester monomers it is no longer present in the carboxylic acid; and that the Examiner admits to this assertion. Appellants argue that Examiner has not provided support that Mitra et al. discloses a repeating unit including a polar group.

Mitra et al. disclose a Unit A monomer, which are derived from monomers with a fluoride counter-ion, i.e. fluoride releasing groups, such as 2-N,N,N-methylammonium ethyl methacrylate, depicted as (A) below, See, page 3, Non-Final office action.

Mitra et al. discloses B unit monomers that are derived from intermediate methacrylic acid esters, depicted as (B) below, of 1-12 carbon, straight or cyclic alcohols, i.e. the B unit monomer is an ester made from methacrylic acid and a 1-12 Art Unit: 1612

carbon straight or cyclic alcohol. Although the Examiner agrees that the straight or cyclic alcohols cited by Mitra et al. are used to make B unit monomers, and that once these B unit monomers, i.e. esters, are formed they no longer possess the hydroxyl functionality, -OH, he does not concede that the resulting B unit monomers do not exhibit a polar nature. The product, which is a methacrylic acid ester, contains a polar or polarizable group, i.e. the ester group. See utexan.edu, page 7, Esters, which teaches that esters are polar compounds. And therefore, the unit B monomer used to produce the polymer of the invention does contain a polar or polarizable group and is different from that of the fluoride-releasing group, compare A and B below. Further, Appellant agrees with the Examiner's assertion that unit B monomers could be made from acrylates, and other polymerizable starting monomers instead of methacrylates, see page 10, 2nd paragraph, Appeal brief. Acrylates or acrylic acid esters also contain a polar or polarizable, ester group.

A. 2-N,N,N-triammonium ethyl methacrylate

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B. a methacrylic acid ester of a 4 carbon alcohol, but the alcohol can be from 1-12 carbons instead of 4

If the two monomers were used to produce the polymer of Mitra et al. it would result in the polymer, a portion which is depicted below. Units A and B are different repeating units. While Unit A has a fluoride releasing group, Unit B contains a polar or polarizable ester group.

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Mitra et al. teach that the polymers are useful for the administration of dentifrice components, i.e. oral care actives, See Non-final office action page 4.

Majeti et al. teach hydrophobic polymers desirable for delivery of oral actives, including whitening agents, such as hydrogen peroxide. And therefore, provides motivation for combining the two references, i.e. the use of hydrogen peroxide as an oral care, i.e. whitening, active.

(2) In response to the 103(a) rejection over Mitra et al. in view of Majeti et al., the combination taken further in view of Aasen et al. from the Final Office Action mailed 06/06/2008 and the Advisory Action dated 09/02/2008, Appellants' argument concerning Mitra et al. and Majeti et al. is the same as discussed above. Appellants take the same position on the applicability of Mitra et al. The Examiner's argument concerning Mitra et al. and Majeti et al. provided above is applicable to this rejection as well.

Further, Aasen et al. teach that the fluoride releasing monomers containing tetrafluoroborate ions are preferred due to their compatibility with virtually all other comonomers, See page 5, Non-final office action, mailed 10/09/2008. Therefore, Aasen et al. provides adequate motivation for combining it with Mitra et al. and Majeti et al.

(3) In response to the 103(a) rejection over Rozzi et al. in view of Majeti et al., from the Final Office Action mailed 06/06/2008 and the Advisory Action dated 09/02/2008, Appellants argue that the Examiner has improperly relied on Rozzi et al. for disclosing a polymer that includes a repeating unit including a polar or polarizable group and a

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repeating unit including a fluoride releasing group, wherein the repeating unit including the polar or polarizable group is different than the repeating unit including the fluoride releasing group. Appellants argue that they have not been able to locate any support for the Examiner's allegation that unit B monomers can be branched or cyclic alcohols. Further, Appellants argue that the branched or cyclic alcohols cited by the Examiner are precursors of the Unit B monomers, and are not monomers themselves, i.e. that once the hydroxy group of the alcohol reacts to form the ester monomers it is no longer present in the carboxylic acid; and that the Examiner admits to this assertion. Appellants argue that Examiner has not provided support that Rozzi et al. discloses a repeating unit including a polar group.

Examiner disagrees, since the disclosure of Rozzi et al. and Mitra et al. is substantially the same concerning the monomers for Unit A and Unit B, Appellant's argument concerning the applicability of Rozzi et al. is the same as that for the applicability of Mitra et al., therefore, the same response to the arguments concerning the A and B monomers is applicable. The Examiner's discussion of Majeti et al. is still applicable.

Rozzi et al. also teaches the same monomers for Unit A and for Unit B and further, the incorporation of hydrophobic hydrocarbon groups such as octadecylacrylate as the Unit C monomer of the polymer; and that the polymers can be used with oral care actives. see Non-Final office action, page 5.

Majeti et al. teach that hydrogen peroxide is an oral care agent and therefore provides the motivation for it combining with Rozzi et al.

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(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Darryl C Sutton/ Examiner, Art Unit 1612

Conferees:

/Frederick Krass/ Supervisory Patent Examiner, Art Unit 1612

/Kathleen Bragdon/ QAS, Technology Center 1600